Clavicin-457

Amoxicillin and Clavulanate Potassium for Oral Suspension USP

457 mg / 5 ml

Route of administration:Oral

COMPOSITION:
Each 5 ml (after reconstitution) contains:
Clavulanate potassium USP equivalent to Clavulanic acid USP 57 mg
Amoxicillin Trihydrate USP equivalent to Amoxicillin USP 400 mg

Dosage form:
Powder for Oral Suspension

Clinical Pharmacology
Pharmacokinetics:
Combining amoxicillin clavulanic acid cause no appreciable alteration of the pharmacokinetics of two drugs with respect to their separate administration. After oral administration, the two components of maximum plasma concentration of about an hour. The absorption is not affected by food, milk, ranitidine or pirenzepine. The distribution of tissues and body fluids of the two components is generally sufficient to achieve antibacterial levels, although the concentration may be a little weak in bronchial secretions and cerebrospinal fluid. The pharmacokinetic profile of amoxicillin and clavulanic acid in children is parallel to that of the adult.

Pharmacodynamics:
CLAVICIN 457 suspension is a formulation of amoxicillin and clavulanic acid. Amoxicillin has a broad spectrum of bactericidal activity against many gram-positive and gram-negative bacterial organisms. Amoxicillin is, however, susceptible to degradation by beta milk meters, and therefore the spectrum of activity does not include organisms which produce these enzymes. The formulation of amoxicillin and clavulanic acid in CLAVICIN 457 suspension protects degradation amoxicillin (beta)-lactamase enzymes and effectively extends the spectrum antibiotic amoxicillin include many bacteria normally resistant to amoxicillin and other (beta)-lactam antibiotics. Amoxicillin acid has been shown to be active against most of the following strains of microorganisms, both in vitro and in clinical infections.

Gram Positive Micro-organisms :
Aerobic: Staphylococcus aureus, coagulase-negative staphylococci (including Staphylococcus epidermidis), Streptococcus pyogenes, Bacillus anthracis, Coryne-bacterium, viridians Strptococcus, Enterococcus faecium, Enterococcus faecalis, Listeria monocyto-genes, Streptococcus agalactiae. Anaerobic Clostridium species, Peptococcus species, Peptostreptococcus species.

Gram-negative microorganisms: Escherichia coli Aerobic, Proteus mirabilis, Proteus vulgaris, Klebsiella, Salmonella, Shigella, Bordetella pertussis, Gardnerella vaginalis, Legionella, Brucella, Neisseria meningitidis, Neisseria gonorrhoeae, Haemophilus influenza, moraxwlla catarrhalis, Pasteurella multocida, Vibrio cholerae Helicobacter pyroli, Yersinia enterocolitica Anaerobes Bacteroides species including B.fragilis, Fusobacterium species.

Indications:
CLAVICIN 457 suspension is indicated for the treatment of patients in the community of acute bacterial sinusitis or pneumonia due to confirmed or suspected β-lactamase-producing pathogens (eg, H. influenzae, M. catarrhalis, H. parainfluenzae, Klebsiella pneumoniae, or methicillin-susceptible S. aureus) and S. pneumoniae with reduced susceptibility to penicillin (eg, penicillin MIC = 2 mcg / ml). CLAVICIN 457 suspension is not indicated for the treatment of infections due to S. pneumoniae with penicillin MICs ⩾ 4 mcg/mL. Data are limited as regards the infections with S. pneumoniae with penicillin MICs ⩾4 mcg/mL.

Contra-indications:
CLAVICIN 457 suspension is against-indicated in patients with a history of allergic reactions to penicillin. It is also against-indicated in patients with cholestatic jaundice /associated with hepatic dysfunction treatment with amoxicillin / clavulanate potassium. CLAVICIN 457 suspension is against-indicated in patients with severe renal impairment (creatinine clearance <30mL/min.) And in hemodialysis patients.

Interactions:
Allopurinol: May increase the risk of allergic reactions or hypersensitivity to amoxicillin.

BCG: Antibiotics may reduce the therapeutic effect of BCG.

Fusidic acid: may decrease the therapeutic effect of penicillin.

Methotrexate: penicillins may reduce the elimination of methotrexate.

Mycophenolate: Penicillins may decrease serum concentrations of the active metabolite (s) of mycophenolate. This effect appears to be the result of altered enterohepatic recirculation.

Probenecid: May increase serum concentrations of penicillins.

Tetracycline derivatives: May decrease the therapeutic effect of penicillin.

Management: Vaccination with a live attenuated vaccine for typhoid (Ty21a) should be avoided in patients treated with antibacterial agents systemic. The use of this vaccine should be postponed until at least 24 hours after the cessation of antibacterial agents.

Warnings and Precautions:
While amoxicillin / clavulanate potassium possesses the characteristic low toxicity of the penicillin antibiotics, periodic assessment of organ system functions, including renal, hepatic and hematopoietic function is recommended if the treatment is longer than for the drug is approved for administration CLAVICIN 457 suspension should be taken every 12 hours with a meal or snack to reduce the possibility of gastrointestinal disorders.

Side effects:
Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of hypersensitivity to penicillin and/or a history of sensitivity to multiple allergens. CLAVICIN 457 suspension should be used with caution in patients with hepatic dysfunction signs. Liver toxicity associated with the use of amoxycillin / potassium clavulanate is usually reversible.

Abuse and dependence Drugs:
Not applicable.

Symptoms of overdose and antidote:
Significant toxicity and mortality has been demonstrated in male and female mice at doses exceeding 5000 mg/kg; in rats at doses estimated at between 1,300 and 2,400 mg/kg; in hamsters at doses in excess of 10000 mg/kg and in the rabbit, with estimated doses between 500 and 1250 mg/kg. In animals, symptoms were demonstrated in a dose-response relationship and diarrhea, vomiting, tachy-cardia, and respiratory distress.

Management of intoxication: There is no specific antidote to an overdose. Treatment consists of haemodialysis and symptomatic measures paying attention to water and electrolyte balance. Administration of medicinal charcoal and gastric lavage is useful only in case of very high overdose.

Dosage and Administration:
Usual dose for the treatment of infection. Patients over 12 weeks (3 months) and older Mild to moderate infections 25/3.6 mg/kg/day bid severe infection and otitis media, sinusitis, lower respiratory offers 25/3.6 mg/kg/day in mild to moderate infections (upper respiratory tract infections, e.g. recurrent tonsillitis, lower respiratory infections and skin and soft tissue infections)

Storage conditions:
Store at a temperature not exceeding 25°C. Protect from sunlight and moisture.
Reconstituted suspension should be stored in a refrigerator (2-8°C) and used within seven days.

Presentation:
70 ml in 100 ml bottle packed in a printed mono carton along with pack insert and silica gel pouch.

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